E E

Will Time

ži. Practitioner's Docket No. 55322 (71699)

PATENT

Express Mail No. EL888965653U

Preliminary Classification:

Proposed Class:

Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129." M.P.E.P. Section 601, 7th ed.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application Assistant Commissioner for Patents Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) AND 1.10*

(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

MAILING

I hereby certify that, on the date shown below, this correspondence is being:

[]	deposited with the United States Postal Service in Washington, D.C. 20231.	an envelope addre	essed to the Assistant Commissioner for Patents,
	37 C.F.R. Section 1.8(a)		37 C.F.R. Section 1.10*
[]	with sufficient postage as first class mail.	[X]	as "Express Mail Post Office to Address" Mailing Label No. EL888965653US (mandatory)
		NSMISSION	
[]	transmitted by facsimile to the Patent and Tradema	ark Office (703)	•
Date:	October 11, 2001	<u> </u>	nih C Zullian

Norah C. Sullivan

*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. Section 1.10(b).

"Since the filing of correspondence under [Section] 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(New Application Transmittal--page 1

Transmitted herewith for filing is the patent application of Inventor(s):

WARNING:

37 C.F.R. Section 1.41(a)(1) points out:

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.63, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(i) is filed supplying or changing the name or names of the inventor or inventors."

For (title):

POLYMER CONTROLLED DELIVERY OF A THERAPEUTIC AGENT

1. Type of Application

This new application is for a(n)

(check one applicable item below)

[X]	Original (nonprovisional)
[]	Design
[]	Plant

WARNING:

Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

WARNING:

Do not use this transmittal for the filing of a provisional application.

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION
TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT
APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

[]	Divisional.
[]	Continuation.
	Continuation-in-part (C-I-P)

2. Benefit of Prior U.S. Application(s) (35 U.S.C. Sections 119(e), 120, or 121)

NOTE: A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a

nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. Section 112. Each prior application must also be:

- (I) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or
- (ii) Complete as set forth in Section 1.51(b); or
- (iii) Entitled to a filing date as set forth in Section 1.53(b) or Section 1.53(d) and include the basic filing fee set forth in Section 1.16; or
- (iv) Entitled to a filing date as set forth in Section 1.53(b) and have paid therein the processing and retention fee set forth in Section 1.21(l) within the time period set forth in Section 1.53(f).

37 C.F.R. Section 1.78(a)(1).

NOTE If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

WARNING:

If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

WARNING:

When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application must be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. Section 1.78(a)(3).

[X] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed

- A. Required for Filing Date under 37 C.F.R. Section 1.53(b) (Regular) or 37 C.F.R. Section 1.153 (Design) Application
 - 28 Pages of Specification
 - 7 Pages of Claims
 - 7 Sheets of Drawing

4.

WARNING:

DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to Section 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. 1.84, see Notice of March 9, 1988. (1990 O.G. 57-62).

NOTE: "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page. . . " 37 C.F.R. Section 1.84(c)).

mınımur	t distance of 1.5 cm. (3/8 inch) down from the top of the page " 37 C.F.R. Section 1.84(c)).				
	(complete the following, if applicable)				
[]	The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. Section 1.84(b).				
[]	Formal Informal				
В.	Other Papers Enclosed Pages of declaration and power of attorney Page of Abstract Other				
Additi	onal Papers Enclosed				
[]	Amendment to claims				
	[] Cancel in this applications claims before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)				
	Add the claims shown on the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims.)				
[]	Preliminary Amendment Information Disclosure Statement (37 C.F.R. Section 1.98) Form PTO-1449 (PTO/SB/08A and 08B) Citations Declaration of Biological Deposit Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence. Authorization of Attorney(s) to Accept and Follow Instructions from Representative Special Comments Other				

5. Declaration or Oath (including power of attorney)

NOTE: A newly executed declaration is not required in a continuation or divisional application provided the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under Section 1.47 then a copy of that declaration must be filed accompanied by a copy of the decision granting Section 1.47 status or, if a nonsigning person under Section 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. Section 1.63(d)(1)-(3).

NOTE: A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and the residence, post office address and country of citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 C.F.R. Section 1.63(a)(1)-(4).

NOTE: A The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.62, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(I) is filed supplying or changing the name or names of the inventor or inventors. 37 C.F.R. Section 1.41(a)(1).

[] Enclosed Executed by

(check all applicable boxes)

[]	inventor(s).
[]	legal representative of inventor(s). 37 C.F.R. Section 1.42 or 1.43.
[]	joint inventor or person showing a proprietary interest on behalf of inventor who
	refused to sign or cannot be reached.

[] This is the petition required by 37 C.F.R. Section 1.47 and the statement required by 37 C.F.R. Section 1.47 is also attached. See item 13 below for fee.

[X] Not Enclosed.

NOTE: Where the filing is a completion in the U.S. of an International Application, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

[] Application is made by a person authorized under 37 C.F.R. 1.41 on behalf of *all* the above named inventor(s).

(The declaration or oath, along with the surcharge required by 37 C.F.R. Section 1.16(e), can be filed subsequently).

			[]	Showing that the filing is authorized. (not required unless called into question. 37 C.F.R. Section 1.41(d))
6.	Inven	torship	Stateme	nt
WARN	ING:			ntors are each not the inventors of all the claims an explanation, including the ownership ims at the time the last claimed invention was made, should be submitted.
The in	ventors	hip for al	l the clai	ims in this application are:
	[]	The sa	me.	
				or
	[]		t claimed is subm	An explanation, including the ownership of the various claims at the time d invention was made, nitted. submitted.
7.	Langu	ıage		
NOTE:	translai	ion of the i is required	non-Englis	igned oath or declaration may be filed in a language other than English. An English sh language application and the processing fee of \$130.00 required by 37 C.F.R. Section d with the application, or within such time as may be set by the Office. 37 C.F.R. Section
	[X] []	Englisl Non-E		
		[]		ached translation includes a statement that the translation is accurate. 37 Section 1.52(d).
8.	Assign	ıment		
	[]	An ass	ignment	of the invention to
		[]	MENT)	hed. A separate [] "COVER SHEET FOR ASSIGNMENT (DOCU-) ACCOMPANYING NEW PATENT APPLICATION" or [] FORM 595 is also attached.
		[X]	will foll	
NOTE:	"If an as	ssignment i	is submittee	ed with a new application, send two separate letters-one for the application and one for

NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment" Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: A newly executed "STATEMENT UNDER 37 C.F.R. Section 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.

9. Certified Copy

Certified copy(ies) of application(s)

	Country		Appln. no.	Filed
from w	hich pr	iority is claimed		
	[]	is (are) attached.		
	[]	will follow.		
NOTE:		eign application forming the Section 1.55(a) and 1.63.	basis for the claim for priority must be refe	erred to in the oath or declaration. 37
NOTE:	applica entitled	tion or International Applica to priority from a prior fore	for which the application being filed direct ation from which this application claims ber ign application, then complete item 18 on to HERE BENEFIT OF PRIOR U.S. APPLICA	nefit under 35 U.S.C. 120 is itself he ADDED PAGES FOR NEW

10. Fee Calculation (37 C.F.R. Section 1.16)

A. [X] Regular application

2		CLAI	MS AS FILED		
Claims	Number Filed	Basic Fee Allowance	Number Extra	Rate	Basic Fee 37 C.F.R. Section 1.16(a) \$740.00
Total Claims (37 C.F.R. Section .16(c))		- 20 =	x	\$18.00	1.10(a) \$740.00
Independent Claims (37 C.F.R. Section 1.16(b))		- 3 =	x	\$84.00	
Multiple Dependent Claim(s), if any (37 C.F.R. Section 1.16(d))		+	\$280.00		

	[] [] [X]	Amendment cancelling extra claims is enclosed. Amendment deleting multiple-dependencies is enclosed. Fee for extra claims is not being paid at this time.
NOTE:	If the fee	es for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the n of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R.
		Filing Fee Calculation \$
	В.	[] Design application (\$330.0037 C.F.R. Section 1.16(f)) Filing Fee Calculation \$
	C.	[] Plant application (\$510.0037 C.F.R. Section 1.16(g)) Filing Fee Calculation \$
11.	Small 1	Entity Statement(s)
	[]	Statement(s) that this is a filing by a small entity under 37 C.F.R. Section 1.9 and 1.27 is (are) attached.
WARNI		"Status as a small entity must be specifically established in each application or patent in which the status is available and desired. Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. The refiling of an application under Section 1.53 as a continuation, division, or continuation-in-part (including a continued prosecution application under Section 1.53(d)), or the filing of a reissue application requires a new determination as to continued entitlement to small entity status for the continuing or reissue application. A nonprovisional application claiming benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) of a prior application, or a reissue application may rely on a statement filed in the prior application or in the patent if the nonprovisional application or the reissue application includes a reference to the statement in the prior application or in the patent or includes a copy of the statement in the prior application or in the patent and status as a small entity is still proper and desired. The payment of the small entity basic statutory filing fee will be treated as such a reference for purposes of this Section." 37 C.F.R. Section 1.28(a)(2). "Small entity status must not be established when the person or persons signing the statement can unequivocally make the required self-certification." M.P.E.P. Section 509.03, 6th ed., rev. 2, July 1996 (emphasis added).
		(complete the following, if applicable)
	[x]	Status as a small entity was claimed in prior application 60/239,498, filed onOctober 11, 2000 from which benefit is being claimed for this application under:
		35 U.S.C. Section [X] 119(e),

			[] 120, [] 121, [] 365(c),	
		and wh	nich status as a small entity is still proper and desired	d.
		[]	A copy of the statement in the prior application is	included.
		Filing	Fee Calculation (50% of A, B or C above)	\$
NOTE:			ull fee paid will be refunded if a small entity status is established y payment of a full fee. The two-month period is not extendable	
12.	Reques	st for In	ternational-Type Search (37 C.F.R. Section 1.104)	(d))
			(complete, if applicable)	
	[]		prepare an international-type search report for that examination on the merits takes place.	ais application at the time when
13.	Fee Pa	yment B	Being Made at This Time	
	[X]	Not En	closed	
		[X]	No filing fee is to be paid at this time. (This and the surcharge required by 37 C.F.I subsequently.)	R. Section 1.16(e) can be paid
	[]	Enclos	ed	
		[]	Filing fee	\$
		[]	Recording assignment (\$40.00; 37 C.F.R. Section 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION.")	\$
		[]	Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached (\$130.00; 37 C.F.R. Sections 1.47 and 1.17(i))\$	

		[]	For processing an application with a specification in a non-English language		
			(\$130.00; 37 C.F.R. Sections 1.52(d) and 1.17(k)))\$	
		[]	Processing and retention fee (\$130.00; 37 C.F.R. Sections 1.53(d) and 1.21(l))\$	
		[]	Fee for international-type search report (\$40.00; 37 C.F.R. Section 1.21(e))	\$	
NOTE:	complete and 1.78	the applic (a)(1), ind	1.21(l) establishes a fee for processing and retaining any apation pursuant to 37 C.F.R. Section 1.53(f) and this, as well icate that in order to obtain the benefit of a prior U.S. applessing and retention fee of Section 1.21(l) must be paid, with	as the cha	anges to 37 C.F.R. Section 1.53 ther the basic filing fee must be
			Total Fees Enclosed		\$
14.	Metho	d of Pay	ment of Fees		
	[]	Check	in the amount of \$		
	[]		Account No in the amount of \$ icate of this transmittal is attached.	<u>.</u>	
NOTE:	Fees show	uld be item	ized in such a manner that it is clear for which purpose the fee	es are paid	l. 37 C.F.R. Section 1.22(b).
15.	Author	ization t	to Charge Additional Fees		
WARNI	NG:	If no fees	are to be paid on filing, the following items should <u>not</u> be con	npleted.	
WARNI	ING:		ly count claims, especially multiple dependent claims, to avoi are authorized.	id unexpec	ted high charges, if extra claim
	[]	The Co	ommissioner is hereby authorized to charge the nd during the entire pendency of this application to	followin Accour	ng additional fees by this nt No
		[]	37 C.F.R. Section 1.16(a), (f) or (g) (filing fees)		
		[]	37 C.F.R. Section 1.16(b), (c) and (d) (presentation	on of ext	ra claims)
NOTE:	paid or the notice of	hese claims fee deficier	fees for excess or multiple dependent claims not paid on filicancelled by amendment prior to the expiration of the time party (37 C.F.R. Section 1.16(d)), it might be best not to author when dealing with amendments after final action.	period set j	for response by the PTO in any
		[]	37 C.F.R. Section 1.16(e) (surcharge for file	ing the	basic filing fee and/or
			New	Application	on Transmittalnage 10 of 13)

	declaration on a date later than the filing date of the application)
[]	37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a).
[]	37 C.F.R. Section 1.17 (application processing fees)

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under Section 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in Section 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. Section 1.136(a)(3).

[] 37 C.F.R. Section 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. Section 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance.

37 C.F.R. Section 1.311(b)).

NOTE: 37 C.F.R. Section 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . issue fee." From the wording of 37 C.F.R. Section 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

NOTE: "... Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. Section 1.26(a).

[X] Credit Account No. <u>04-1105</u>.

[] Refund

		·	SIGNATURE OF PRACTITIONER
Reg. N	No. 48,	399	John B. Alexander (type or print name of practitioner)
Tel. N	o.: (61	7) 439-4444	
,	(Dike, Bronstein, Roberts & Cushman Intellectual Property Practice Group EDWARDS & ANGELL, LLP P. O. Box 9169 Boston, MA 02209
[X]	Incor	rporation by reference of added pages	
	(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)		
	[]	Plus Added Pages for New Application Application(s) Claimed	Transmittal Where Benefit of Prior U.S.
			Number of pages added1
	[]	Plus Added Pages for Papers Referred to in Ite	m 4 Above Number of pages added
	Plus added pages deleting names of inventor(s) named on prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application. Number of pages added		
	[]	Plus "Assignment Cover Letter Accompanying	g New Application" Number of pages added
		Added page1	

(Added Page(s) for Special Comments for New Application Transmittal)

ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: See 37 C.F.R. Section 1.78.

17. Relate Back

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. Section 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. Section 120, 121 or 365(c). (35 U.S.C. Section 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. Section 119, 365(a) or 365(b).) For a c-I-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the

(complete the following, if applicable)

reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice

of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

[X]Amend the specification by inserting, before the first line, the following sentence:

A. 35 U.S.C. Section 119(e)

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)." 37 C.F.R. Section 1.78(a)(4).

[X]"This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

60/239,498	October 11, 2000 "
60/239,385	October 11, 2000 "
/	

[X] Statement Where No Further Pages Added

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

[X] This transmittal ends with this page.